

### REMARKS

Claims 1-52 are pending in the application, with claims 1-2, 15-47 and 49-52 having been withdrawn from consideration. Claims 3-14 and 48 are under examination. Reconsideration is requested.

Claims 3 and 5 have been amended to correct minor informalities and to recite a particularly preferred feature in Claim 3. No new matter has been added.

The drawings were objected to for minor informalities. New drawings are filed herewith.

The Examiner noted that no Information Disclosure Statement had been filed in the application. A PTO 1449 is filed herewith, along with copies of the references cited.

The disclosure was objected to for lack of complete information. Amendment to the specification will be made as soon as the ATCC depository information is received by the undersigned.

#### Rejection Under 35 U.S.C. § 112, first paragraph

Claims 3-14 and 48 were rejected under 35 U.S.C. §112, first paragraph, as failing to provide an enabling disclosure without complete evidence that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of biological materials. Information on the ATCC Deposit will be forwarded as soon as it is received by the undersigned.

#### Rejection Under 35 U.S.C. § 112, second paragraph

Claim 5 was rejected under 35 USC §112, second paragraph, as being indefinite. The Examiner noted that the claim is vague and indefinite in the recitation of "a DNA sequence corresponds to SEQ ID NO:2 because SEQ ID NO:2 is an amino acid sequence. Claim 5 has been amended to clarify that the DNA encodes a sequence corresponding to SEQ ID NO:2.

Claim 3 was objected to because the abbreviation MSP-1<sub>42</sub> was used without definition in its first occurrence. Claim 3 has been amended to insert the full name of the protein fragment.

Rejection Under 35 U.S.C. § 102

Claim 3 was rejected under 35 U.S.C. §102(b) as being anticipated by Kumar et al., 1995, Molecular Medicine 1, pages 325-332. It was the Examiner's position that Kumar et al. disclose a recombinant vector pGEX3 comprising a DNA sequence encoding MSP-1<sub>42</sub>. Claim 3 was also rejected under 35 U.S.C. §102(b) as being anticipated by Chang et al., 1996, Infection and Immunity 64: pages 253-261. It is the Examiner's position that Chang et al. disclose a recombinant vector pGEX3 comprising a DNA sequence encoding MSP-1<sub>42</sub>. Claim 3 has been amended to recite the characteristic that expression of said vector under suitable conditions results in a protein that retains its native folding, and is believed to be free of the rejection. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 9-10 were rejected under 35 U.S.C. §102(b) as being anticipated by Kumar et al., 1995. It is the Examiner's position that the claims are drawn to a method for producing and purifying recombinant *P. falciparum* MSP-1<sub>42</sub> protein comprising growing a host cell containing vector expressing said protein, lysing said host cells to recover said recombinant protein, and that Kumar et al. disclose a method of producing and purifying recombinant MSP-1<sub>42</sub> from *P. falciparum*, electroplating into *E. coli*, growing bacterial cells in the presence of IPTG to induce the high expression of recombinant protein and recovering recombinant MSP-1<sub>42</sub> to be used as a vaccine in Aotus monkeys.. This rejection is traversed for the following reasons.

It is respectfully submitted that Kumar et al. do not disclose a method wherein host cells are grown such that a vector expressing *P. falciparum* MSP-1<sub>42</sub> expresses a soluble MSP-1<sub>42</sub> protein, and the host cells are lysed so that and MSP-1<sub>42</sub> protein is recovered that retains its native folding, as recited in claim 9. Furthermore, Kumar et al. do not disclose such a method wherein the expression of the vector is by induction with IPTG at a temperature range of 24°C-27°C, as recited in claim 10. Reconsideration and withdrawal of the rejection are respectfully

requested.

Rejections under 35 U.S.C. § 103

Claims 9-14 and 48 were rejected under 35 U.S.C. §103 as being unpatentable over Kumar et al 1995, Molecular medicine 1, pages 325-332 in view of short Protocols in Molecular Biology (Ausubel). According to the Examiner's position, Kumar teaches a method of producing and purifying recombinant *P. falciparum* MSP-142 from vector pGEX2, and further, Ausubel teaches protein expression in various vectors including thioredoxin fusion proteins, growing the expression vectors containing DNA encoding proteins that are induced by IPTG at various temperatures in the presence of fungicides, antibiotics and purifying proteins from *E. coli* containing pET vectors using Ni-NTA column to remove endotoxin, etc. Applicants respectfully submit that the combination of Kumar et al. with Ausubel is no more than an "invitation to experiment", which would have required Applicants to pick and choose among the myriad protocols described in Ausubel, and would not have been reasonably expected to result in the invention claimed in claims 9-14 and 48. Reconsideration and withdrawal of the rejection is respectfully requested.

Applicants appreciate the Examiner's indication that Claims 4-8 are free of the prior art.

Appl. No. 10/057,531  
Amendment dated December , 2003  
Reply to Office Action of August 4, 2003

Favorable reconsideration of Claims 3-14 and 48 is respectfully requested. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

Respectfully submitted,

Date: 2/4/04

C. A. Hobbs

Ann S. Hobbs, Ph.D.  
Registration No. 36,830  
Venable  
P.O. Box 34385  
Washington, D.C. 20043-9998  
Telephone: (202) 344-4000  
Telefax: (202) 344-8300